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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,292	08/08/2001	James J. Cawley	PC10888AJAK	3108

7590

04/14/2003

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,292	CAWLEY ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/21/2003 as Paper Number 5.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4-18 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 and 6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response filed January 21, 2003 as Paper Number 5 to election requirement in Office Action mailed October 08, 2002 as paper number 3 is acknowledged and entered.
2. Please note that the correct Serial Number of your Application under prosecution is 09/924,292, not 09/942,292 as recited in the Response to Restriction Requirement referred to *supra* (i.e., Paper Number 5, filed January 21, 2003). Please ensure that the correct U.S. Serial Number for this application is cited in all future correspondence with this Office.
3. Claims 1-24 are pending.

Restriction/Election

4. Applicants' election with traverse of Group I, Claims 1-3 and 19 filed January 21, 2003 as Paper Number 5 to election requirement in Office Action mailed October 08, 2002 as paper number 3 is acknowledged and entered. . Because applicant did not distinctly and specifically present the reasons for traversal, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 4-18 and 20-24 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Claims 1-3 and 19 are examined on merits.

Information Disclosure Statement

6. Applicants' Information Disclosures (i.e., IDSs) filed August 8, 2001 as paper number 2 and on January 21, 2003 as paper Number 6 have been made of record and considered.

Priority

7. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. Based upon filing of U.S. Provisional Application Number 60/224,089, instant non-provisional U. S. Application Number 09/924,292 is given the benefit of filing date of August

09, 2002.

Claim Rejections - 35 U.S.C. § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 2-3 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to a biotransformation process carried out by a microorganism selected from a group of fungi that are available from American Type Culture Collection (because applicants mention an ATCC number for those microorganisms) and "mutants thereof".

10. The mutants of fungi referred to *supra* are therefore essential to the invention recited in those claims. Therefore, those mutants (i.e., those giving better yield of product according to specification (Page 17, Lines 1-6 and 19-28) should also be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. From the disclosure on lines cited *supra*, the referred mutants are not available to the public. If the microorganism (s) is not so obtainable or available, a deposit of the microorganism (s) in a recognized depository may satisfy the requirements of 35 U.S.C. §112.

In order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807 which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit.

11. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 1-3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrases "suitable conditions" in claim 1 and "suitable mutants" in Claims 2-3 render those claims unclear and indefinite because it is not clear how one can determine with clarity and accuracy when the conditions/mutants are suitable and what may be a suitable condition/mutant for one may not be suitable for another. Applicant is advised to define the metes and bounds of the term "suitable".

All other claims depend directly or indirectly from the rejected claims (e.g., 1) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 103

13. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

15. Claims 1-3 and 19 are rejected under 35 U.S.C. § 103 (a) as obvious over Kiener (Angen. Chem. Int. Ed. Engl. Volume 31, 1992) in view of Burns et al (U. S. Patent 6,361,979).

Claims recite a process for microbial oxidation of methyl group of a bicyclic heteroaromatic compound (e.g., 2-methylquinoline) to corresponding carboxylic acid (e.g., 2-quinoline carboxylic acid) by a number of microorganisms (e.g., fungi) or mutants of said microorganisms, wherein said microorganism is intact and said carboxylic acid is isolated from the reaction mixture via solvent extraction and subsequent chromatography of said solvent extract.

Kiener teaches a bacterial or fungus mediated process to microbially oxidize a single methyl group on a heteroaromatic compound to make heteroaromatic monocarboxylic acid (Page 774, Column 1, Lines 32-39 and Table 1). Kiener also teaches that bacteria and fungi mediated oxidation of alkyl side chains on heteroarenes is an art-recognized process (Page 774, Column 1, Lines 32-33). Please note that since Kiener teaches the yields of the product of reaction (Page 774, Column 2, Lines 63-68), Kiener has intrinsically taught isolation of

said monocarboxylic acid produced through microbial oxidation of single methyl group on a heteroaromatic.

Kiener, however, does not disclose microbial oxidation of a methyl group on a bicyclic aromatic compound.

Burns et al. teach fungi mediated oxidation of a bicyclic heteroaromatic compound (e.g., 2-methylquinoxaline) to corresponding carboxylic acid (e.g., 2-quinoxaline carboxylic acid) by a number of fungi such as those claimed or mutants thereof, wherein said microorganism is intact and said carboxylic acid is isolated from the reaction mixture via solvent extraction and subsequent chromatography of said solvent extract (Column 19, Lines 5-47). Please note that Burns et al. teach a method wherein, microbial oxidation of a methyl group on a bicyclic heteroaromatic is carried out by same microorganisms under same conditions and products are isolated according to the same steps as is recited in the instant invention, i.e. the prior art process is according to the same steps, applying the same microorganisms and culture media as the instantly claimed process. Thus, the prior art intrinsically discloses the same process as is recited in the claimed invention.

One having ordinary skill in the art would have been motivated to modify Kiener's teachings according to the beneficial teachings from Burns et al. by incorporating a bicyclic aromatic methyl group carrying compound for oxidation of said methyl group to corresponding monocarboxylic acid, because both Kiener (Page 774, Column 1, Lines 32-39 and Table 1; Page 774, Column 2, Lines 63-68) and Burns et al. (Column 19, Lines 5-47) references teach oxidation of a side chain methyl group on an aromatic compound to corresponding monocarboxylic acid.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kiener's teachings according to the beneficial teachings from Burns et al. because each one of the cited references teach a process to biologically oxidize the methyl group on an aromatic compound to corresponding monocarboxylic acid. The deficiency of a bicyclic heteroaromatic compound in teachings from Kiener is remedied by the beneficial teachings from Burns et al.

None of the prior art references cited above teach the bicyclic heteroaromatic compound carrying the methyl group to be 2-methylquinoline and corresponding carboxylic

acid to be 2-quinoline carboxylic acid. However, the adjustment of particular conventional working conditions (e.g., substrates and resulting products from the substrate in a given process) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.


Conclusion

16. No Claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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Patent Examiner
Art Unit 1651
(703) 605-1196

April 10, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER